K063832

3.0 510(k) Summary

Sponsor: Synthes (USA)
1301 Goshen Parkway
West Chester, PA 19380
(610) 719-5000

MAR 0 7 2007

Contact: Jennifer Perks
Synthes (USA)
1301 Goshen Parkway
West Chester, PA 19380
610-719-6941

Device Name: Synthes (USA) Elbow Hinge Fixator

Classification: The classification of the Synthes Elbow Hinge Fixator as per 21 of the Code of Federal Regulations, Section 888.3030 – Single/Multiple Component metallic bone fixation appliances and accessories

Predicate Device: Stryker-Dynamic Joint Distractor II

Device Description: The Synthes Elbow Hinge Fixator consists of two rods, which are interconnected through a riveted joint, allowing a hinge-like movement. The rods are made of carbon fiber reinforced PEEK, and the joint is made of stainless steel. The overall length of the device is 180mm and the achievable range of motion averages 270 degrees.

Intended Use: The Synthes Elbow Hinge Fixator is intended for supplementary treatment of complex, unstable elbow injuries when early functional stress must be limited due to persistent ligament instability.

The indications for guided joint bridging with external fixators are:
-Delayed treatment of dislocated and stiff elbows
-Chronic, persistent joint instability
-Acute joint instability after complex ligament injuries
-Unstable elbow fractures
-Additional stabilization of post-operative unstable internal fixation

The Elbow Hinge Fixator is compatible with the components of the Synthes Large External Fixator for adults, and with the components of the Synthes Medium External Fixator for children and small stature adults.

Substantial Equivalence: Documentation is provided which demonstrates the Synthes Elbow Hinge Fixator to be substantially equivalent to other legally marketed devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Synthes (USA)
% Ms. Jennifer Perks
Regulatory Affairs Specialist
1301 Goshen Parkway
West Chester, PA 19380

MAR 0 7 2007

Re: K063832
Trade/Device Name: Elbow Hinge Fixator
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: LXT
Dated: December 22, 2006
Received: December 26, 2006

Dear Ms. Perks:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120 Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SYNTHES®

2.0 Indications for Use

510(k) Number (if known): _____

Device Name: Synthes (USA) Elbow Hinge Fixator

Indications for Use:

The Synthes Elbow Hinge Fixator is intended for supplementary treatment of complex, unstable elbow injuries when early functional stress must be limited due to persistent ligament instability.

The indications for guided joint bridging with external fixators are:
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Prescription Use X AND/OR Over-The-Counter Use_____
(Per 21 CFR 801.109) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

K063832

(510(k) Number)